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EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary	Application No.	Applicant(s)	
	10/087,782	ROSIER ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *8-16, 25-29, 32-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 17-24, 30-31, 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1-7, 17-24, 30, 31 and 40) in Paper No.9, filed on 20 June 2003 is acknowledged. It is noted that claim 35 which is drawn to a pharmaceutical composition comprising the polypeptide of SEQ ID NO:31, is inadvertently included in both the elected Group I which is drawn to the nucleic acid and to Group III, which is drawn to the polypeptide. Therefore, claim 35 which belongs with Group III, will not be examined.

Applicants' first ground of traversal is that searching for Groups I, II and IV would not be burdensome to the Examiner, because the subject matter of Groups I, II and IV is sufficiently related, hence a thorough search for any one group would encompass a search for the other groups. Applicants also submit that claims of Groups II and IV are related to the claims of Group I as processes of making and of using the product of Group I, therefore, the claims of the non-elected method Groups II and IV should be rejoined with the product claims of Group I in the event that the product claims are found allowable.

Applicants further submit that the nucleic acids of SEQ ID Nos: 1 through 30 have a common functional property in that they are all exons of the same gene, which encodes the ABCC11 protein, therefore, sequences of SEQ ID Nos:1-30 are not independent and distinct, and should not be restricted.

These grounds of traversal have been fully considered but are not deemed persuasive. The inventions of Groups I-VII are drawn to patentably distinct inventions

and are classified in different classes and sub-classes and each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search, (MPEP § 808.02). Also, contrary to Applicants' assertion a single search would not reveal art pertinent to all of the recited inventions. Thus, searching more than one group would pose undue burden on the Examiner.

Applicants' traversal that nucleic acids of SEQ ID Nos: 1-30 are not independent and distinct, because they are exons which encode ABCC11 protein is not found persuasive, because, instant specification describes the ABCC11 protein of the instant invention as comprising 1382 amino acid residues. Therefore, only SEQ ID NO:1 is long enough to encode for the ABCC11 protein of the instant invention.

In the event where the product of Group I is found allowable, method claims of making and using the nucleic acid of Group I will be rejoined, so long as the method claims do not precipitate new grounds of rejections.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 8-16, 25-29, 32-39 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Claim objections

2a. Claims 1-7, 17-20 are objected to because of the following informalities:

Claims 1-7 are objected to because they recite non-elected SEQ ID Nos.

Claims 17-20 are objected to, insofar as they depend on claim 1. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Instant claims 1-7,17-24, 30-31 and 40 are directed to an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:1, and an isolated nucleic acid encoding the polypeptide of SEQ ID NO:32. Instant specification describes the claimed nucleic acid as belonging to ABC protein sub-family and designates as ABCC11, (see page 5, sections 007-009). The specification further states that the ABCC11 gene is likely to be involved in the transport of organic anion transporters, such as cysteinyl leukotrienes, anionic drugs, such as methotrexate as well as neutral drugs conjugated to acidic ligands, such glutathione (GSH), glucuronate or sulfate, (papge 7, section 013). The specification also states that it would be reasonable to suggest that the ABCC11 protein of the instant invention could share functional similarities with ABCC4, and /or ABCC5, (page 5, section 008). Instant specification also states that the ABCC11 gene is mapped in a region located in the 16q12 locus of the human chromosome 16, which is a regions statistically linked with two genetic pathologies, PKD and PKC. Thus Applicants suggest that the ABCC11 gene might be involved in the etiology of PKC, (top of page 7).

However, although instant specification makes the above assertions, it does not show whether the protein encoded by the claimed nucleic acid actually transports any of the above mentioned substances. Neither does the instant specification establish a link between PKD or PKC and the ABCC11 protein of the instant invention. For example,

instant specification does not demonstrate whether the ABCC11 protein of the instant invention is over-expressed, under-expressed or completely lacking in patients suffering from PKC or PKD.

Instant specification asserts that the ABCC11 of the instant invention is similar to ABCC4 and ABCC5 in that it appears to also lack the extra-N terminal domain which is present in other members of this family. It has been shown that overexpression of ABCC4 (also known as MRP4, multi-drug resistant protein 4) severely impaired the antiviral efficacy of resistance to PMEA (9-(2-phosphonylmethyoxyethyl)adeneine and azidothymidine monophosphate and other nucleotide drugs, (see Schuetz et al, Nature Medicine, vol.5, No.9, pages 1048-1051, 1999, abstract and page 1048). Wijnholds et al (PNAS, Vol.97,no.13, pages 7476-7481, 2000) also disclose that ABCC5 (MDR5) is an organic anion transporter with a remarkable ability to confer resistance to base and nucleotide analogs, (see page 7476). However, Applicants have not shown that the ABCC11 protein of the instant invention confers any drug resistance. The fact that the ABCC11 of the instant invention appears to lack the extra-N terminal domain does not establish a physiological role for this protein. There is little doubt that, after further characterization, and once the specific function and role of the protein encoded by the claimed nucleic acid is ascertained, it would have a specific, substantial and credible utility, however, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility.

The claimed invention is directed to a nucleic acid encoding a polypeptide of as yet undetermined function or biological significance, therefore, unless Applicants demonstrate the physiological significance or the biological role of the instant nucleic acid and the protein it encodes, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

3b. Claims 1-7,17-24, 30-31 and 40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification only discloses a deduced amino acid sequence for the protein encoded by the claimed nucleic acid, it does not disclose an activity for it, neither does it establish a nexus between it and a physiological conditions. Therefore the skilled artisan would not know how to use the nucleic acid, comprising the nucleotide sequence set forth in SEQ ID NOS:1 or the protein encoded, thereby.

Should Applicants establish an activity for the polypeptide of SEQ ID NO:31 encoded by the claimed nucleic acid of SEQ ID NO:1, instant specification would still fail to adequately describe and enable for an isolated nucleic acid comprising at least 80%, 85%, 90%, 95% or 98% to SEQ ID NO:1, as recited in instant claims 3 and 4. Applicants do not teach which regions of the nucleic acid of SEQ ID NO:1 are critical for the functional integrity of the nucleic acid, neither do Applicants teach whether "all" possible fragments comprising eight contiguous nucleotides of SEQ ID NO:1, would display the activity of the nucleic acid of SEQ ID NO:1. The specification does not

provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a nucleic acid that comprises 80%, 85%, 90%, 95% or 98% of SEQ ID NO:1 that would encode a functional protein, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a nucleic acid or a polypeptide encoded thereby, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention, an isolated nucleic acid comprising a encoding 80%, 85%, 90%, 95% or 98% SEQ ID NO:1, would be undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5, 6, 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claim 5 is rejected as vague and indefinite reciting "An isolated nucleic acid that hybridizes *under high stringency conditions*....", which is a conditional term and renders the claim indefinite. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be " *high*

stringency".

4b. Claims 6 and 7 recite "ABCC11 ...", which renders the claims unclear, because more than one gene can be known for the same acronym. Applicant is advised to recite the full name of the gene corresponding to this acronym in the first independent claim to obviate this rejection.

Claim rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless —
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 5-6 are rejected under 35 U.S.C § 102(b) as being anticipated by Strausberg et al, (December, 1999).

Strausberg et al. teach an isolated nucleic acid that comprises shares 100% identity to instant SEQ ID NO: 1, from nucleotide 4540 to 4862. See attached copies of the comparison of SEQ ID NO:1 claimed in the instant invention and the sequences of the reference (SEQUENCE COMPARISON 'A'). The nucleic acid disclosed in the Strausberg et al reference comprises at least eight or at least 15 consecutive nucleotides of the nucleotide sequence of SEQ ID NO:1. Therefore, Strausberg et al. reference clearly anticipates instant claims 5 and 6 in the absence of any evidence to the contrary.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
August 7, 2003

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